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REQUIREMENTS FOR SUBMISSION OF DATA

NEEDED FOR TOXICOLOGICAL ASSESSMENT OF CHEMICALS TO BE FLOWN ON MANNED SPACECRAFT

NASA JSC Toxicology Group
Environmental Factors Branch
Habitability & Environmental Factors Division

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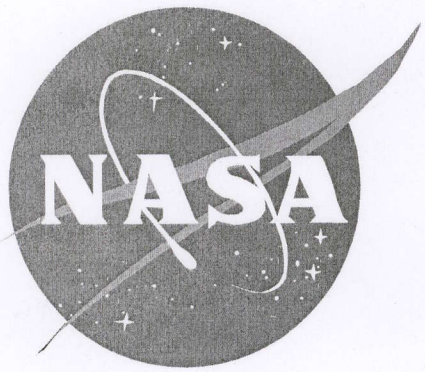

National Aeronautics and Space Administration
Lyndon B. Johnson Space Center
Houston, Texas

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REVISION LOG

VERSION	CHANGE DESCRIPTION	RELEASE DATE
Baseline (JSC 25607)	Initial release	10/1994
Baseline (JSC 27472)	Assigned new document number	9/1996
Revision A	Major revision of entire document	3/1999
Revision A.2	Updated links	8/12/2003
Revision B	Added requirements for part numbers of all hardware sub-systems. Added statement citing potential inclusion of ECLSS assessments in HMST. Added request for battery chemistry data. Modified text concerning biological assessments.	6/25/2006

CONTENTS

APPLICABLE DOCUMENTS

NSTS/ISS 13830 Revision C. Payload Safety Review and Data Submittal Requirements For Payloads Using the: Space Shuttle, International Space Station. July 1998

SSP-30599 Revision A. Safety Review Process. International Space Station Alpha Program. January 11, 1995.

ABREVIATIONS AND ACCRONYMES

BRB	Biosafety Review Board
BSL	Biological Safety Level
DSO	Detailed Supplementary Objectives
DTO	Detailed / Development Test Objectives
ECLSS	Environmental Control and Life Support Systems
GFE	Government Furnished Equipment
GSRP	KSC Ground Safety Review Panel
HMST	Hazardous Materials Summary Table
ISS	International Space Station
JSC	Lyndon Johnson Space Center
KSC	Kennedy Space Center
L-	Launch minus
MSDS	Material Safety Data Sheet
NASA	National Aeronautics and Space Administration
PO	Payload Organization
PSRP	Payload Safety Review Panel
RME	Risk Mitigation Experiment
SDP	Safety Data Package
SMART	Safety and Mission Assurance Review Team
SRP	ISS Safety Review Panel
THL	Toxicological Hazard Level
V-1	Verification-1
V-2	Verification-2

I. WHY THESE REQUIREMENTS ARE NEEDED AND THEIR SCOPE

Data on chemical and biological materials to be flown in the pressurized volumes of habitable spacecraft, including the International Space Station (ISS), are needed by NASA JSC toxicologists to assess the toxicity and assign hazard levels. This document defines submission schedules and establishes requirements for the types and format of these data. Adherence to these timelines and requirements will help eliminate unnecessary delays or obstacles to the toxicological approval of materials for flight.

Toxicity Hazard Levels (THL) are assessed only for chemicals, although biological materials will also be listed in Hazardous Materials Summary Tables (HMSTs) and HazMat data files. Assessment of hazards associated with biological agents will be conducted separately by the JSC Biosafety Review Board (BRB) who will assign a BioSafety Level that will be listed in HMSTs and HazMat data files. Assessment of radioactive materials and assessment of materials for flammability will be conducted by the JSC Radiation Working Group and the JSC Material Sciences Branch respectively. Their assessment results will be included in HMSTs and HazMat data files. Thus, in addition to data that the hardware provider supplies separately to the JSC BRB, certain information on biological materials proposed for flight within pressurized volumes of habitable spacecraft must also be submitted to NASA JSC Toxicology in accordance with the guidelines described in this document.

Chemicals that may not pose any problems from a toxicological standpoint may be deleterious to a habitable spacecraft's Environmental Control and Life Support Systems (ECLSS) function and adversely affect crew health in an indirect manner. As such, it is necessary that all chemicals also be assessed for ECLSS compatibility by ECLSS engineering personnel based on data sharing between the NASA JSC Toxicology Group and ECLSS engineers. Details concerning the information for ECLSS compatibility assessments can be found at the NASA JSC Toxicology Web site at: http://www1.jsc.nasa.gov/toxicology. The ECLSS Hazard Level may eventually be reflected in the HMST.

II. APPLICABILITY OF THESE REQUIREMENTS

These requirements apply to items that contain liquids, gases, gels, greases, powders/ particulates, radioisotopes, or biological materials are located in or may be introduced into the habitable pressurized volume of ISS or U.S. operated spacecraft. These include, but are not limited to science payloads, government furnished equipment (GFE), risk mitigation experiments (RMEs), detailed / development test objectives (DTOs), detailed supplementary objectives (DSOs), life science experiments, and medical studies. They apply even to materials that are obviously non-toxic, e.g. water or compressed air, since it may become necessary to identify them if they were to escape in-flight.

These requirements do not apply to flight hardware that contains no chemicals, nor to offgas products from the hardware, but do apply to all chemicals or biologicals contained in the hardware. Food, drinking water in the galley, items in the Crew Preferences Kit, and structural components are excluded from these requirements.

III. WHO MUST PROVIDE THE DATA AND TO WHOM

The hardware provider or payload organization representative must supply data on chemical and biological materials. "Payload Organization" (PO) is used in a generic sense to refer to a group or individual who is responsible for the development, construction, integration, or flight preparation of a flight article and who is thoroughly familiar with its composition and function (e.g. a principal investigator, payload coordinator, or payload integration manager). Information pertaining to chemical and biological materials requested in this document should be sent to the NASA JSC Toxicology e-mail address (jsc-txcology@mail.nasa.gov) and to the applicable safety organization such as: the JSC Payload Safety Review Panel (PSRP), ISS Safety Review Panel (SRP), Safety and Mission Assurance Review Team (SMART), or KSC Ground Safety Review Panel (GSRP).

The PO is also required to provide separate data submittals to the JSC BRB, the JSC Radiation Working Group, the JSC Materials Sciences Branch, or the JSC Energy Systems Division Battery Group when biological, radioactive, flammable, and/or batteries are planned for use in the payload. Submission of data to the NASA JSC Toxicology Group and/or ECLSS Engineering does not fulfill the POs data submittal obligations to any of these other groups.

IV. REFLOWN AND PREVIOUSLY ASSESSED MATERIALS

A list of material compositions, concentrations, and amounts must be submitted for every mission/flight. These requirements apply equally to materials being flown for the first time and to materials that have previously flown and/or have previously been assessed, with the following exceptions. Material safety data sheets and data on physical or chemical properties need not be submitted if a material is identical in composition to that flown by the hardware provider or PO representative and assessed by the NASA JSC toxicologists for a previous mission/flight. If there are no changes from the previous mission/flight, the hardware provider or PO representative may submit a copy of the previous verified Hazardous Material Summary Table (HMST). If only minor changes are planned, a marked-up copy of the previously approved HMST, showing the planned changes, may be submitted.

V. WHAT SPECIFIC TYPES OF DATA ARE NEEDED

A list of the information that must be provided for toxicological assessment of each type of chemical and biological material is given below. A form that provides space to fill in the required information may be obtained from the NASA JSC lead toxicologist assigned to that flight (hereafter referred to as the mission toxicologist), or by downloading from the NASA JSC Toxicology Web site at: http://www1.jsc.nasa.gov/toxicology.

A. For all chemicals and biologicals, the following types of data are needed:
   - The mission/flight on which the item will be flown (ascent and descent, if known)
   - The name of the experiment or hardware and of all subsystems that contain the chemicals / biologicals
   - The experiment hardware subsystem which contains the item
   - A brief description of the protocol of the experiment, including mixing, heating, or other processing of materials which affects their composition or concentration
   - The apparatus subsystem which contains the item
   - The number of items of each type
   - The part numbers of the hardware and subsystems that contain the chemicals / biologicals
   - The locations (i.e. middeck or module) during launch, on-orbit stowage, processing, and re-entry
   - Which data, if any, are proprietary
   - Material Safety Data Sheet (MSDS), if available (except for common chemicals)
   - The name, affiliation, phone, fax numbers, and e-mail addresses of one or more contact persons who can provide and verify information

B. For liquids, solutions, gels, mixtures, powders, and particulates, the following additional data are needed:

- The chemical identity of each component (for commercial undefined mixtures, e.g. sera, broths, and extracts, provide commercial identification, e.g. Hyclone FetalClone I® fetal bovine serum)
- The "as loaded" concentration of each component in a mixture or solution
- The volume or weight of each separately contained portion of an item
- The number of separately contained portions of each item to be flown (i.e. the number of identical samples)
- The particle size range of powders and particulates
- The pH of all solutions in launch, on-orbit, and landing configurations. Note any expected changes in pH due to on orbit activities and/or storage)
- The identity and amounts of anticipated reaction products, if known

C. For gases, the following additional data are needed:

- The chemical identity of each gas
- The concentration of each gas
- The volume of the containment vessel
- The pressure and mass of the gas

D. For metals to be processed in a furnace, the following additional data are needed:

- The number of samples of identical composition (for each composition)
- The identity, weight and/or percentage of each component in each sample
- The dimensions and/or surface area of each sample
- The sample containment system (e.g. glass ampule, crucible)
- The processing temperatures
- The processing times, including warm up duration, duration at nominal processing temperature, and cool down duration
- The melting and boiling points of each component, if known
- The fraction of the sample being heated at any one time and, for zonal melting experiments, the width and rate of movement of the heated zone
- The evaporation rate or vapor pressure of each component metal at maximum planned processing temperature and at maximum runaway temperature (assuming two worst-case credible failures of the temperature control system), if known

- The weight lost by each sample during furnace processing, if known
- The atmosphere (inert gas, vacuum, ambient, etc.) in the furnace
- The method of cooling the furnace
- The maximum number of samples processed at one time

E. For combustion experiments, the following additional data are needed:
- The identity, amount per sample, and number of samples of each material to be burned
- The composition of the pre-combustion atmosphere
- The anticipated combustion products and their amounts, if known
- The planned disposal method for combustion products after each test
- A description of the sample holders and containment systems during storage, during processing, and after processing

F. For hardware containing biological materials:
- The identity, number / amount per sample, and number of samples of biological materials
- Whether biologicals are trapped in a matrix (e.g. gel) or free (e.g. in suspension)
- The identity, number / amount per sample, concentrations and number of samples of nutrient media / food
- Radioactive components, if any

G. For batteries:
- The chemical composition of batteries or the manufacturers type and model number (e.g. Panasonic CR2032 lithium manganese dioxide button cells)
- The size and total number of batteries
- The number of batteries installed in the hardware and the number of spares to be launched
- An MSDS, if available

VI. WHEN THE DATA MUST BE SUBMITTED

The timelines for submission of data are listed in Appendix A. Earlier submissions are welcome and strongly recommended. Data submittal requirements are consistent with NSTS/ ISS-13830 for hardware being reviewed by the PSRP and SSP-30599 (Safety Review Process) for hardware being reviewed by the SRP and SMART.

VII. HOW THE DATA SHOULD BE FORMATTED

Considerable flexibility is allowed in the format for submission of data as long as all the required data are presented clearly and legibly. An example of a recommended format for the submission of the required data for solutions of chemicals is shown in Appendix B. Recommended formats for other types of materials may be obtained by e-mail or fax from the mission toxicologist (see Section III) or from the NASA JSC Toxicology web page on the Internet: www1.jsc.nasa.gov/toxicology/.

VIII. HOW PROPRIETARY DATA WILL BE HANDLED

NASA JSC Toxicology discourages submission of proprietary data due to restrictions in handling. At the time that data are submitted to NASA JSC Toxicology, the hardware provider or payload organization representative must designate which specific data (e.g. the identity, but not the concentration of each ingredient) should be treated as proprietary. In addition to the proprietary data, alternative, non-proprietary text (e.g. "an organic buffering agent" instead of "Tris-HCl") should be provided for inclusion in the HMST. Dissemination of proprietary data will be limited to NASA and contractor personnel who have a valid need to know. These include NASA and contractor toxicologists, microbiologists, ECLSS specialists, materials scientists, NASA flight surgeons, crewmembers and possibly others, on a case-by-case basis. After the flight, proprietary data will be destroyed, except that archived by the toxicologists in restricted-access locations. If the hardware provider or payload organization representative requires a more restricted distribution for specific items, a request should be submitted to the NASA JSC chief toxicologist.

APPENDIX A
TIMELINES FOR SUBMISSION OF DATA

Adherence to the required timelines for submission of data is important for NASA JSC Toxicology to be able to prepare and distribute written hazard assessments before safety reviews. Any material compatibility issues with ISS-ECLSS are best addressed at the early stages of payload development. The required timelines are as follows:

I. DURING EARLY STAGES OF DESIGN AND/OR CONSTRUCTION OF FLIGHT ARTICLES (optional, but very beneficial)

An early submission of a preliminary list of all candidate chemical and biological materials, as well as preliminary support data (process temperatures, durations, etc.) will enable the toxicologist to make an early toxicological assessment and allow ECLSS engineering to assess all potential hardware and environmental compatibility impacts in a timely manner. This will help the hardware provider or PO representative to ensure that planned containment and other safeguards are adequate before the final design or construction of the flight article.

It is especially important for payloads with large numbers of different materials that lists of chemical or biological materials be submitted as early as possible. If a long list (>40 materials) is submitted at the designated time for the Phase 0/I or Phase II safety review (see below), it may not be possible to assess all of them before the safety review. Therefore, if the hardware provider or payload organization representative has already identified some of the materials at an early date, he/she is encouraged to send even a partial list to the mission toxicologist. The data for the remaining materials from the long list should be submitted as they are identified or in accordance with the schedule below, whichever is earlier.

II. FORTY-FIVE DAYS PRIOR TO UPCOMING SAFETY REVIEWS

A current materials list must be sent by the hardware provider or PO representative to the mission toxicologist and to the executive officer of the cognizant review panel and others listed in Section III of this document no later than the time that a safety data package (SDP) is submitted to the appropriate NASA safety review panel for each review. A review meeting is normally scheduled to occur forty-five days after the SDP is submitted. If the materials list includes changes from a previously submitted list, such changes must be clearly identified. The materials list may be incorporated into the safety data package in addition to the separate list sent to the mission toxicologist. The toxicologist will assess the materials in the list and prepare an HMST prior to the safety review meeting.

Hardware providers or PO representatives for flight articles that do not undergo a full NASA safety panel review before a given flight should submit materials data at or before L-4.5 months in order to permit completion of the mission HMST and verification-1 process, described below.

Overview of the two-step process to verify the data in the HMSTs.

The Verification-1 ("V-1") process assures that the mission toxicologist has a complete and accurate list of all materials that are being considered for flight on a given mission (a "candidate" list).

The Verification-2 ("V-2") process assures that the mission toxicologist has a complete and accurate list of the materials selected by the PO from the V-1 candidate list that were actually loaded into the flight hardware.

III. THREE MONTHS BEFORE LAUNCH (Spacehab, Other Cargo Carriers, ISS Elements) or TWO MONTHS BEFORE LAUNCH (Shuttle Middeck): COMPLETION OF VERIFICATION-1 (V-1) OF MATERIALS DATA IN THE CANDIDATE HMST

Since the final HMST and the verification of all data on candidate materials (V-1) must be complete by L-3 months, it is recommended that data submission to the mission toxicologist occur no later than L-4.5 months for cargo carriers and ISS elements, L-3.5 months for middeck items, or as early as possible. This timeframe should also be followed for submitting data to ECLSS engineering for review. All data for chemical and biological materials in the HMST for each flight article will be verified for accuracy and completeness by the designated representative of the hardware provider or PO representative as follows:

1) The mission toxicologist will send the current HMST and a V-1 form to the hardware provider or PO representative, who will clearly write any necessary corrections on the HMST and promptly fax or e-mail it back, along with the signed V-1 form, to the mission toxicologist. The hardware provider or PO representative will mark the appropriate check box on the V-1 form to indicate if corrections were required to the HMST. (If the flight article is a Spacehab payload, all transmissions of HMST and V-1 forms must be sent through the Spacehab Integration Contractor representative, who will also sign the V-1 form).

2) Any required revisions will be incorporated into the HMST by the mission toxicologist who will send the revised HMST and a new V-1 form back to the hardware provider or PO representative for verification.

3) This process will be repeated until the hardware provider or PO representative can check the V-1 box indicating that no further changes to the HMST are required. This verified HMST is considered the final candidate materials list for that item.

Policy on Changes to the HMST

Changes in the materials data are permissible up until the time the V-1 form is signed. **After the V-1 form has been signed, no further additions of new materials or increases in concentrations or quantities per container will be accepted.** Rare exceptions to this rule will require the approval of the Flight Manager, the chairman of the cognizant Safety Review Panel, and the Mission Toxicologist. Deletions or reductions in quantities per container or concentrations and changes in location are permitted after V-1. Substitution of sample materials listed in the approved and verified HMST among individual containers in the same experiment system after V-1 is permitted.

IV. AT THE TIME OF "LOADING" OF CHEMICALS / BIOLOGICALS INTO HARDWARE: VERIFICATION-2 (V-2) OF HMST DATA TO REFLECT "AS LOADED" MATERIALS

Within approximately 2 weeks after the V-1 is completed or approximately 2 weeks before chemical / biological materials are loaded into their hardware, the mission toxicologist will send a V-2 form and a copy of the V-1-verified HMST to the hardware provider or PO representative for use during loading of the chemicals / biologicals into the hardware (hereafter referred to as "loading"). The V-2 form is to be completed by the PO at the time that materials are loaded into their flight hardware or as soon as feasible thereafter. The V-2 must be completed before the hardware will be accepted by KSC personnel for installation into a spacecraft for launch.

During loading, the PO representative marks up the V-1-verified HMST, noting all deletions, reduced amounts or concentrations, changes in location in the experiment system, or any other allowed changes as described under "Policy on changes to the HMST". The pre-flight HMST to be marked up will be the final V-1-verified version that was provided to the hardware provider or PO representative by the mission toxicologist for use during loading. The markups to the V-1-verified HMST should accurately reflect the materials that are actually loaded into the hardware, showing the actual amounts and concentrations loaded. The PO will cross out any materials listed in the HMST that are not loaded and initial each record of the HMST representing a sample that is loaded.

In the V-2 form, the PO will mark the appropriate checkbox to indicate whether corrections have been made to the HMST, sign and date the V-2 form, and immediately

send the HMST (if there were changes) and the signed V-2 form by fax or by e-mailing scanned copies to the mission toxicologist for review. However, for experiments conducted in a Spacehab, POs should send these documents to the Spacehab Payload Integrator, who will also sign the V-2 form, then send the documents to the mission toxicologist. If documents are sent by fax, the PO should notify the mission toxicologist by telephone before transmission.

The mission toxicologist reviews all corrections to the HMST for compliance with the PSRP's 'Policy on Changes to the HMST'. If acceptable, the mission toxicologist notifies the Spacehab Payload Integrator, PO, and/or KSC Payload representative, as appropriate, that the "As Loaded" HMST is approved for flight. For "late load" items, PO representatives must provide to the mission toxicologist a pager or cell phone number for an individual responsible for loading, in case of questions during the review of the marked-up HMST.

For "late load" items, the original of the signed V-2 forms and marked-up HMSTs must be sent to the mission toxicologist within 24 hours after launch.

The PO must notify the mission toxicologist before launch if, for any reason, (e.g. a leak is detected after completion of the V-2) the hardware is to be launched with a different configuration than listed in the completed V-2 form.

For hardware and payloads launched to the ISS on non-U.S. spacecraft, the process for acquisition and verification of materials data (V-1 and V-2 procedures) will be consistent with agreements negotiated between the U.S. and the International Partners/Participants.

V. HMST V-2 PROCESS FOR LAUNCH SLIPS / LAUNCH SCRUBS:

After a payload has been loaded and verified, if a launch delay requires that the chemicals in the payload be refurbished, the V-2 process must be repeated, whether the same or a different subset of approved candidate chemicals are selected from the V-1 HMST for loading. Only materials that were included as candidates in the V-1-verified HMST may be loaded for that flight.

APPENDIX B

RECOMMENDED DATA FORMAT FOR SOLUTIONS

Name of experiment or hardware:_____

Acronym for experiment or hardware:_____ Part #:_____ Date submitted:_____

Launch vehicle:_____ Launch Date:_____ Return vehicle:_____ Return date:_____

Flight# up:___ Flight# down:____ ISS#:_____ Storage Location:_____ Use Location:_____

Contact person:_____Organization:_____

Phone:_____ Fax:_____ e-mail:_____

Brief summary of the experiment, including process conditions:_____

_____

_____

Experiment Subsystem (e.g. vial #3, syringe A, bag, dish, tray, canister)	ID Label (Visible to Crew)	Chemicals/ Biologicals/Reaction Products (including pH of acids, bases, & buffers) List each component on a separate line.	Maximum Concentration	Maximum # of Samples	Maximum Amount per Sample	Comments

☐ **Check this box if the data are Proprietary**